

Application No. 10/086,992

Response dated September 3, 2004

Reply to Notice of Non-Compliant Amendment dated August 27, 2004

### REMARKS/ARGUMENTS

Applicants have carefully reviewed the Office Action mailed on February 4, 2004. With this amendment, claims 5, 35, 43, 47, and 54 are amended. Please cancel the second instance of claim 5, and cancel claim 51, without prejudice. Claims 1-50 and 52-58 remain pending.

As an initial matter, it appears as though claim 5 appears twice in this application. In order to correct this matter, Applicants have amended the first instance of claim 5 to include the subject matter of the second instance of claim 5 and then cancelled the second instance. Applicants respectfully submit that these amendments correct this matter.

Claim 35 is objected to because of informalities. The Examiner indicated that the phrase "a the connector" should be changed to "a connector". Claim 35 is now amended according to the Examiner's suggestion. Applicants respectfully submit that this amendment overcomes the objection.

Claims 1-13, 16, 20-28, 30, and 33-42 are rejected under 35 U.S.C. §102(b) as being anticipated by Eder et al. in EP 806220 A2. The Examiner indicated that Eder et al. disclose a medical device as claimed. We disagree. Independent apparatus claims 1, 25, 40, and 42 all recite that the distal section of the medical device includes a linear elastic nickel-titanium alloy. Similarly, independent method claims 35 and 39 each recite the step of providing a distal section comprising a linear elastic nickel-titanium alloy. Thus, each of these claims recites a distal section including linear elastic nickel-titanium alloy. Eder et al. does not teach or suggest a medical device, or a method of manufacturing a medical device, that includes a distal section including linear elastic nickel-titanium alloy.

The distinction between linear elastic and super elastic nickel-titanium alloys is significant. Super elastic nickel-titanium alloys are used extensively throughout the medical device industry due to their remarkable ability to recover from exorbitant amounts of strain. This property is often utilized in medical devices because it allows, for example, guidewires to easily navigate the often tortuous vasculature without plastically deforming. Eder et al. discuss some of these benefits and disclose that their guidewire is designed to take advantage of these characteristics by virtue of being made from super elastic materials. Eder et al. at column 9, line 34 through column 10, line 18.

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Linear elastic nickel-titanium alloys, in contrast, do not possess these super elastic properties but rather exhibit distinct mechanical properties. (Please see, for example, page 6, line 14 through page 7, line 19 of the current specification.). For example, linear elastic nickel-titanium alloys do not display a typical "super elastic plateau" or "flag region" in its stress/strain curve. Instead, as recoverable strain increases, the stress continues to increase in a more linear relationship until plastic deformation begins. Applicants have determined that in some instances, linear elastic properties, derived from the use of linear elastic nickel-titanium alloys, can desirably impact the properties of a medical device. For example, in some instances, it has been found that including a linear elastic nickel-titanium distal section on a medical device allows the device to exhibit superior pushability when navigating the tortuous vasculature. (Please see page 7, lines 7-14 of the current specification). Thus, the invention as claimed includes an alternative material (i.e., linear elastic nickel-titanium alloys instead of super elastic alloys) than that taught or suggested by Eder et al.

Because of the differences between the claimed invention and the disclosure of Eder et al., independent claims 1, 25, 35, 39, 40, and 42 can be readily distinguished from Eder et al. Accordingly, it is believed that these claims and all claims depending therefrom are patentable over Eder et al. and in condition for allowance. Applicants respectfully request withdrawal of the rejection of these claims under 35 U.S.C. §102(b).

Claims 43 and 44 are rejected under 35 U.S.C. §102(e) as being anticipated by Richardson et al. (U.S. Patent No. 6,673,025). Amended claim 43 now recites that the distal portion of the core wire includes a linear elastic nickel-titanium alloy. Richardson et al. does not teach or suggest a distal portion of a core wire including a linear elastic nickel-titanium alloy. (See, for example, Richardson et al. at column 9, lines 38-40). Accordingly, it is believed that claim 43 is now patentable over Richardson et al. Because claim 44 depends from claim 43, it is also patentable over Richardson et al. for the same reason, and because it adds significant elements to distinguish it further from the art.

Claims 14, 15, 17-19, 29, 31, 32, 54, and 57 are rejected under 35 U.S.C. §103(a) as being unpatentable over Eder et al. in view of Gambale et al. (U.S. Patent No. 5,144,959). As described above, independent claims 1 and 25 recite a distal section including a linear elastic nickel-titanium alloy. Amended independent claim 54 similarly recite that the distal section

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includes a linear elastic nickel-titanium alloy. The recitation of the distal section including a linear elastic nickel-titanium alloy distinguishes the claimed invention from Eder et al. Gambale et al. similarly fails to disclose or teach a distal section including a linear elastic nickel-titanium alloy. Therefore, claims 1, 25, and amended claim 54 are allowable over Eder et al. and Gambale et al. Because claims 14, 15, and 17-19 depend from claim 1, because claims 29, 31, and 32 depend from claim 25, and because claim 57 depends from claim 54, these claims are also allowable for these reasons, and because they include significant elements that distinguish them further from the art.

Claims 45-48 and 51-52 are rejected under 35 U.S.C. §103(a) as being unpatentable over Richardson et al. in view of Sepetka et al. (U.S. Patent No. 4,832,047). Claim 51 is cancelled and its substance incorporated into claim 47. It should be first noted that the Examiner indicated on page 4 of the office action that "it is well known in the art to provide a core made of a linear elastic nickel-titanium alloy". However, as pointed out above, Applicants respectfully submit that the art cited by the Examiner does not teach or suggest the use of linear elastic nickel-titanium alloys, but rather discloses the use of super elastic materials. As such, Applicants hereby request that the Examiner withdraw any rejections based on this statement or else provide evidence sufficient in order to maintain any such rejections.

As to claims 45-46, claim 43 is amended to recite that the distal portion of the core wire includes a linear elastic nickel-titanium alloy. Neither Richardson et al. nor Sepetka et al. disclose this feature. Accordingly, amended claim 43 is believed to be in condition for allowance. Because claims 45-46 depend from claim 43, they are also allowable for this reason, and because they add significant elements to distinguish them further from the art. As to claims 47, 48, and 52, claim 47 is amended to similarly recite that the distal portion of the core wire includes a linear elastic nickel-titanium alloy. Accordingly, amended claim 47 is believed to be in condition for allowance. Because claims 48 and 52 depend from claim 47, they are also allowable for this reason, and because they add significant elements to distinguish them further from the art.

Claims 47, 49, 50, and 52 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gambale et al. in view of Sepetka et al. As described above, amended claim 47 now

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recites that the distal portion of the core wire includes a linear elastic nickel-titanium alloy. Neither Gambale et al. nor Sepetka et al. disclose this feature. Accordingly, amended claim 47 is believed to be in condition for allowance. Because claims 49, 50, and 52 depend from claim 47, they are also allowable for the same reason, and because they add significant elements to distinguish them further from the art.

Claim 53 is rejected under 35 U.S.C. §103(a) as being unpatentable over Gambale et al. in view of Sepetka et al., and further in view of Morrison et al. (U.S. Patent No. 4,748,986). Amended claim 47 now recites that the distal portion of the core wire includes a linear elastic nickel-titanium alloy. None of Gambale et al., Sepetka et al., or Morrison et al. disclose this feature. Accordingly, amended claim 47 is believed to be in condition for allowance. Because claim 53 depends from claim 47, it is also allowable for the same reason, and because it adds significant elements to distinguish it further from the art.

Claims 54-56 are rejected under 35 U.S.C. §103(a) as being unpatentable over Richardson et al. in view of Eder et al. As described above, amended claim 54 now recites that the distal portion of the core wire includes a linear elastic nickel-titanium alloy. Neither Richardson et al. nor Eder et al. disclose this feature. Accordingly, amended claim 54 is believed to be in condition for allowance. Because claims 55-56 depend from claim 54, they are also allowable for this reason, and because they add significant elements to distinguish them further from the art.

Claim 58 is rejected under 35 U.S.C. §103(a) as being unpatentable over Richardson et al. in view of Eder et al., and further in view of Sepetka et al. As described above, amended claim 54 now recites that the distal portion of the core wire includes a linear elastic nickel-titanium alloy. None of Richardson et al., Eder et al., or Sepetka et al. disclose this feature. Accordingly, amended claim 54 is believed to be in condition for allowance. Because claim 58 depends from claim 54, it is also allowable for the same reason, and because it adds significant elements to distinguish it further from the art.

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Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their attorney,

Date:

September 3, 2004

  
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